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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,282	11/10/2003	Samuel Chackalamannil	CV01185K1X	4919

24265 7590 03/23/2007

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,282	CHACKALAMANNIL ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-8, 11-16, 19-27, and 29-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,17,18 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03 August 2004 and 08 June 2005.

DETAILED ACTION

Status of the Claims

1. Claims 1-39 are pending in the application, with claims 1-8, 11-16, 19-27, and 29-39 having been withdrawn from consideration, in response to the restriction requirement submitted on December 1, 2006. Accordingly, claims 9-10, 17-18, and 28 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election of the claims of Group II, namely claims 9-39, in the reply filed on January 3, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on January 3, 2007.

3. Applicants' election of (1) the compound of the formula in claim 17, and (2) the therapeutic condition species, acute coronary syndrome, in the reply filed on January 3, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-16, 19-27, and 29-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on January 3, 2007. The elected species of claim 17 was found to be free of the prior art and thus the search was broadened to the general formula II.

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on August 3, 2004 and June 8, 2005 is acknowledged.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the instant application contains legal phraseology, namely "said". Additionally, the abstract of the instant application contains two paragraphs. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9-10, 17-18, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating a therapeutic condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to a method of treating a therapeutic condition comprising administering a compound of formula II.

(2). ***State of the Prior Art***:

The skilled artisan would view that the treatment of a vast array of any therapeutic condition, is highly unlikely. The prior art, however, contains examples of working examples of the compound of formula II used in thrombin receptor antagonist assays as well as platelet aggregation inhibition assays but no examples for treating acute coronary syndrome comprising administering a compound of formula II (see U.S. Patent 6,063,847, table in column 314 as an example).

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the art of any therapeutic condition, including acute coronary syndrome, is extremely high.

(4). ***Predictability of the Art***:

The treatment of a vast array of therapeutic conditions, not only acute coronary syndrome, with a compound of formula II is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the

breadth of the claims. The claims encompass the administration of a compound of formula II as a treatment for any therapeutic condition, not only for cardiovascular diseases such as acute coronary syndrome.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to the method for treatment of not only any therapeutic condition, but acute coronary syndrome in particular, comprising administrating a compound of formula II of the instant application is non-existent.

The disclosure of the compounds of formula II of the instant invention is adequate (pages 22-33, tables 4-8 and examples 1-92).

(7). ***Working Examples***:

The working examples in the specification showing examples of compounds of Formula II are adequate (pages 22-33, tables 4-8 and examples 1-92). The prior art, however, contains working examples of the compound of formula II used in thrombin receptor antagonist assays as well as platelet aggregation inhibition assays but no examples for treating acute coronary syndrome comprising administering a compound of formula II (see U.S. Patent 6,063,847, table in column 314 as an example). Thus, the working examples show examples of compounds of formula II, not how to treat any therapeutic condition, including acute coronary syndrome, with the compounds of formula II.

Note that lack of a working example to treat any therapeutic condition, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See

MPEP 2164.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of a compound represented by formula II to treat any therapeutic condition. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples as discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chackalamannil et al. (U.S. Patent 6,063,847) as evidenced by Gerlitz et al. (U.S. 2003/0022354).

Chackalamannil et al. teach thrombin receptor antagonists according to formula I, and more specifically, compounds of formula IA, which are the same as the compounds of the instant

claimed invention, when X is O, Y is =O, R^1 is methyl, R^3, R^8, R^9, R^{10}, and R^{11} are all hydrogen, B is -CH=CH-, and Het is optionally substituted pyridyl (column 2, formula I; and column 4, formula IA).

Chackalamannil et al. also teach compounds of formula I can be used as an antithrombotic, anti-platelet aggregation, anticoagulant or anticancer agent (column 5, lines 43-46).

Furthmore, Chackalamannil et al. teach a method for treating acute coronary syndrome as well as other cardiovascular diseases such as myocardial infarction (column 5, line 38). It is noted that Gerlitz et al. teach a method of treating acute coronary syndrome such as myocardial infarction (page 2, paragraph [0016]). Thus, Gerlitz et al. teach myocardial infarction is an acute coronary syndrome.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102 (b).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 9 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Chackalamannil et al. (U.S. Patent 6,063,847) and claim 1 of Chackalamannil et al. (U.S. Patent 6,326,380). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of Chackalamannil et al. (U.S. Patent 6,063,847) and claim 1 of Chackalamannil et al. (U.S. Patent 6,326,380) is directed at a composition of formula I, which is the same composition of formula I used in a method of treating a therapeutic condition in the instant claim 9. Thus the composition of formula I is not patentably distinct between Chackalamannil et al. (U.S. Patent 6,063,847), Chackalamannil et al. (U.S. Patent 6,326,380), and the instant application.

8. Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application Chackalamannil et al. (US 2006/0079684) and claim 1 of copending Application Thiruvengadam et al. (US 2006/0173189). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of Chackalamannil et al. (US 2006/0079684) is directed at a composition of formula I, which is the same composition of formula I used in a method of treating a therapeutic condition in the instant claim 9 and claim 1 of Thiruvengadam et al. (US 2006/0173189) is directed at a method of preparing Compound I, which is the same composition

of formula I used in a method of treating a therapeutic condition in the instant claim 9. Thus the composition of formula I is not patentably distinct between Chackalamannil et al. (US 2006/0079684), Thiruvengadam et al. (US 2006/0173189), and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

9. Claim 9 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of Chackalamannil et al. (U.S. Patent 6,063,847) and claim 9 of Chackalamannil et al. (U.S. Patent 6,326,380) in view of Chackalamannil et al. (U.S. Patent 6,063,847) as evidenced by Gerlitz et al (US 2003/0022354) as applied to claims 9-10 above.

10. Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45 and 51 of copending Application Chackalamannil et al. (US 2005/0130975) and claim 1 of copending Application Veltri et al. (US Serial Number 11/613,450) in view of Chackalamannil et al. (U.S. Patent 6,063,847) as evidenced by Gerlitz et al. (US 2003/0022354) as applied to claims 9-10 above.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER